## REMARKS

This Reply is intended to be completely responsive to the Non-Final Office Action dated February 5, 2009.

#### Status

Claims 1-17 are pending in this Application.

Claims 1-17 stand rejected.

Independent claims 1 and 13 have been amended.

Applicant believes that the rejections raised by the Examiner have been addressed and the Application is in condition for allowance. Reconsideration and allowance of pending Claims 1-17 is respectfully requested.

# **Examiner Interview Conducted March 4, 2009**

On March 4, 2009, Applicant's attorney conducted a telephone interview with Examiner Koharski during which the current amendments to independent claims 1 and 13 were discussed in view of the art of record. It is Applicant's understanding that the Examiner agrees that independent claims 1 and 13, as amended, overcome the rejections based upon Spievack et al., U.S. Patent No. 5,871,484, Wilcox et al., U.S. Patent No. 5,681,289, Chappius, U.S. Patent Publication No. 2001/021852, and Sasso et al., U.S. Patent Publication No. 2004/0225292.

# Claim Rejections - 35 U.S.C. § 102(b)

On pages 2-3 of the Office Action, the Examiner rejected claims 1-6, 9-11 and 13-17 as being anticipated by <u>Spievack et al.</u> For the reasons discussed below, Applicant respectfully asserts that claims 1-6, 9-11 and 13-17 are not anticipated <u>Spievack et al.</u>

Independent claim 1, as amended, recites a "device for delivering a substance to a bone" comprising, in combination with other elements, "an insert disposed inside the cannulated bone-screw shaft ... wherein the insert is movable between: a first position wherein none of the one or more insert fenestrations align with the one or more bone-screw fenestrations such that at least a portion of the shaft of the insert substantially prevents material from entering the cannulated portion of the bone-screw through the one or more bone-screw fenestrations." Independent claim 13, as amended, recites a "device for delivering a substance to a bone" comprising, in combination with other elements, "an insert disposed inside the cannulated bone-screw shaft such that at least a portion of the shaft of the insert prevents at least some material from entering the cannulated portion of the bone screw through all of the one or more bone-screw fenestrations." The amendments to claims 1 and 13 are supported by the application as originally filed. See e.g., Application, paragraph [0037] and FIG. 4.

As agreed to during the interview with Examiner Koharski, Spievack et al. does not disclose "an insert disposed inside the cannulated bone-screw shaft ... wherein the insert is movable between: a first position wherein none of the one or more insert fenestrations align with the one or more bone-screw fenestrations such that at least a portion of the shaft of the insert substantially prevents material from entering the cannulated portion of the bone-screw through the one or more bone-screw fenestrations," as recited in independent claim 1, and does not disclose "an insert disposed inside the cannulated bone-screw shaft such that at least a portion of the shaft of the insert prevents at least some material from entering the cannulated portion of the bone screw through all of the one or more bone-screw fenestrations," as recited in independent claim 13. In contrast, Spievack et al. discloses a "sponge 30" positioned within an "orthopedic screw 90" including "vias 94." See col. 5, lines 58-65 and Fig. 12. However, neither "sponge 30" nor any other element of Spievack et al. is "an insert disposed inside the cannulated bonescrew shaft ... wherein the insert is movable between; a first position wherein none of the one or more insert fenestrations align with the one or more bone-screw fenestrations such that at least a portion of the shaft of the insert substantially prevents material from entering the cannulated portion of the bone-screw through the one or more bone-screw fenestrations," as recited in

independent claim 1, or "an insert disposed inside the cannulated bone-screw shaft such that at least a portion of the shaft of the insert prevents at least some material from entering the cannulated portion of the bone screw through all of the one or more bone-screw fenestrations," as recited in independent claim 13.

In view of the amendments to independent claims 1 and 13 and the arguments set forth above, Applicant respectfully asserts that independent claims 1 and 13 and dependent claims 2-6, 9-11 and 14-17 are not anticipated by <u>Spievack et al.</u>, under 35 U.S.C. § 102(b).

## Claim Rejections - 35 U.S.C. § 103(a)

Rejection of Claims 7-8 Under 35 U.S.C. § 103(a) as Obvious over Spievack et al. in View of Sasso et al or Chappius

On pages 4-5 of the Office Action, the Examiner rejected claims 7-8 under 35 U.S.C. § 103(a) as unpatentable over <u>Spievack et al.</u> in view of <u>Sasso et al.</u> or in view of <u>Chappius</u>. Applicant asserts that independent claim 1, as amended, recites a combination of subject matter that is allowable under 35 U.S.C. § 103(a). Consequently, Applicant respectfully asserts that claims 7 and 8, that depend from claim 1, are also patentable.

As agreed to during the interview with Examiner Koharski, neither <u>Spievack et al.</u>, <u>Sasso et al.</u>, nor <u>Chappius</u>, disclose, teach, or suggest "an insert disposed inside the cannulated bone-screw shaft ... wherein the insert is movable between: a first position wherein none of the one or more insert fenestrations align with the one or more bone-screw fenestrations such that at least a portion of the shaft of the insert substantially prevents material from entering the cannulated portion of the bone-screw through the one or more bone-screw fenestrations," as recited in independent claim 1. In contrast, <u>Spievack et al.</u>, discloses a "sponge 30" positioned within an "orthopedic screw 90" including "vias 94." <u>See col.</u> 5, lines 58-65 and Fig. 12. <u>Sasso et al.</u> discloses an "clongate guiding portion 14." <u>See e.g.</u>, Paragraph [0031] and Figs. 2 and 3. <u>Chappius</u> discloses an "anchor 10." <u>See e.g.</u>, Paragraph [0027] and Fig. 1. As such, neither

Spievack et al., Sasso et al., nor Chappius, disclose, teach, or suggest all of the elements of the "device for delivering a substance to a bone" as recited in independent claim 1.

Because the references cited by the Examiner fail to disclose, teach, or suggest at least one element of independent claim 1, as amended, Applicant respectfully asserts that the "device for delivering a substance to a bone" recited in dependent claims 7 and 8 would not have been obvious in view of <u>Spicvack et al.</u>, alone or in any proper combination with either <u>Sasso et al.</u> or <u>Chappius under 35 U.S.C.</u> § 103(a).

# 2. Rejection of Claim 12 Under 35 U.S.C. § 103(a) as Obvious over Spievack et al. in View of Wilcox et al.

On pages 5-6 of the Office Action, the Examiner rejected claim 12 under 35 U.S.C. § 103(a) as unpatentable over <u>Spievack et al.</u> in view of <u>Wilcox et al.</u> Applicant asserts that independent claim 1, as amended, recites a combination of subject matter that is allowable under 35 U.S.C. § 103(a). Consequently, Applicant respectfully asserts that claim 12, that depends from claim 1, is also patentable.

As agreed to during the interview with Examiner Koharski, neither <u>Spievack et al.</u> nor <u>Wilcox et al.</u>, disclose, teach, or suggest "an insert disposed inside the cannulated bone-screw shaft ... wherein the insert is movable between: a first position wherein none of the one or more insert fenestrations align with the one or more bone-screw fenestrations such that at least a portion of the shaft of the insert substantially prevents material from entering the cannulated portion of the bone-screw through the one or more bone-screw fenestrations," as recited in independent claim 1. In contrast, <u>Spievack et al.</u> discloses a "sponge 30" positioned within an "orthopedic screw 90" including "vias 94." <u>See</u> col. 5, lines 58-65 and Fig. 12. <u>Wilcox et al.</u> discloses both "a sump or bladder 100" and "a sump or bladder 110." <u>See</u> col. 9, lines 14-18, col. 10, lines 42-43, and Figs. 8-13. As such, neither <u>Spievack et al.</u>, nor <u>Wilcox et al.</u>, disclose, teach, or suggest all of the elements of the "device for delivering a substance to a bone" as recited in independent claim 1.

Because the references cited by the Examiner fail to disclose, teach, or suggest at least one element of independent claim 1, as amended, Applicant respectfully asserts that the "device for delivering a substance to a bone" recited in dependent claim 12 would not have been obvious in view of Spievack et al., alone or in any proper combination with either Wilcox et al. under 35 U.S.C. § 103(a).

#### Conclusion

Claims 1-17 are pending in the present Application. Claims 1 and 13 have been amended. Favorable reconsideration of the application, as amended, is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date March 12, 2009

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